

(3) Color additive mixtures for drug use made with FD&C Blue No. 1 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* (1) The color additive FD&C Blue No. 1 for use in coloring drugs generally shall conform in specifications to the requirements of § 74.101(b).

(2) FD&C Blue No. 1 Aluminum Lake shall be prepared in accordance with the requirements of § 82.51 of this chapter.

(c) *Uses and restrictions.* (1) FD&C Blue No. 1 may be safely used for coloring drugs, including drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice.

(2) FD&C Blue No. 1 Aluminum Lake may be safely used for coloring drugs intended for use in the area of the eye, in amounts consistent with current good manufacturing practice, subject to the restrictions on the use of color additives in § 70.5(b) and (c) of this chapter.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 1 shall be certified in accordance with regulations in part 80 of this chapter.

[47 FR 42565, Sept. 28, 1982, as amended at 59 FR 7638, Feb. 16, 1994]

§ 74.1102 FD&C Blue No. 2.

(a) *Identity.* (1) The color additive FD&C Blue No. 2 shall conform in identity to the requirements of § 74.102(a)(1).

(2) Color additive mixtures for use in ingested drugs made with FD&C Blue No. 2 may contain only those diluents that are suitable and that are listed in part 73 of this chapter as safe for use in color additive mixtures for coloring drugs.

(b) *Specifications.* (1) The color additive FD&C Blue No. 2 for use in coloring surgical sutures shall conform to the following specifications and shall be free from impurities other than those named to the extent that such

impurities may be avoided by current good manufacturing practice:

Sum of volatile matter at 135 °C (275 °F) and chlorides and sulfates (calculated as sodium salts), not more than 15 percent.

Water insoluble matter, not more than 0.4 percent.

Isatin-5-sulfonic acid, not more than 0.4 percent.

Isomeric colors, not more than 18 percent.

Lower sulfonated subsidiary colors, not more than 5 percent.

Lead (as Pb), not more than 10 parts per million.

Arsenic (as As), not more than 3 parts per million.

Total color, not less than 85 percent.

(2) The color additive FD&C Blue No. 2 for use in coloring ingested drugs shall conform to the specifications in § 74.102(b).

(c) *Uses and restrictions.* (1) The color additive FD&C Blue No. 2 may be safely used for coloring nylon (the copolymer of adipic acid and hexamethylene diamine) surgical sutures for use in general surgery subject to the following restrictions:

(i) The quantity of color additive does not exceed 1 percent by weight of the suture.

(ii) The dyed suture shall conform in all respects to the requirements of the United States Pharmacopeia XX (1980).

(iii) When the sutures are used for the purposes specified in their labeling, the color additive does not migrate to the surrounding tissues.

(iv) If the suture is a new drug, an approved new drug application, pursuant to section 505 of the Federal Food, Drug, and Cosmetic Act, is in effect for it.

(2) The color additive FD&C Blue No. 2 may be safely used for coloring ingested drugs in amounts consistent with current good manufacturing practice.

(d) *Labeling.* The label of the color additive and any mixtures prepared therefrom intended solely or in part for coloring purposes shall conform to the requirements of § 70.25 of this chapter.

(e) *Certification.* All batches of FD&C Blue No. 2 shall be certified in accordance with regulations in part 80 of this chapter.

[48 FR 5260, Feb. 4, 1983, as amended at 49 FR 10090, Mar. 19, 1984]